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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,766	11/20/2003	Fritz Kirchhofer	33728/US	8384

7590 08/24/2007  
David E. Bruhn  
DORSEY & WHITNEY LLP  
Intellectual Property Department  
50 South Sixth Street, Suite 1500  
Minneapolis, MN 55402-1498

EXAMINER
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WITCZAK, CATHERINE

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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08/24/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/717,766	<b>Applicant(s)</b> KIRCHHOFFER, FRITZ	
	<b>Examiner</b> Catherine N. Witczak	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 June 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2 and 4-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2 and 4-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 2, 4-6, 8-13, 18, 20-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Yasumichi (JP P2000-84078A) which was filed on 3/28/2000 and listed in the IDS filed on 2/17/04. The Japanese patent discloses in figures 1 & 4-8 a cannula system comprising a cannula support comprising a thread turning in a first direction (10,11) and another thread turning in a second, generally opposite direction (15,16); and a protective cap 12 for covering a point of a needle having a thread (18,19) engageable with said thread turning in said second generally opposite direction, at least one latching element 13 arranged on the cannula support, the cap comprising a complementary latching element 17, and an injection device 1 having a thread (7,8) engageable with said thread turning in the first direction. With respect to claim 2, wherein the term "inner" is seen to be proximal and the term "outer" is seen to be distal.

With respect to claims 9-13 & 18, wherein the device has a latching element 13 on the cannula support and a corresponding latching element 17 on the cap, wherein the device is fully capable of having a releasable manner with element 17 not being pushed past element 13 to provide an easier cover, while if the element 17 is pushed past element 13 would create a non-releasable manner.

With respect to claims 20-26, the reference disclosing a cannula system comprising a Cannula support comprising a first portion 5 having a first diameter, a second portion having a second diameter greater than the first diameter the second portion comprising an exterior thread, which is seen to be a

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distal thread (15,16), turning in a first direction and an interior thread, seen as a proximal thread (10,11), turning in a second, generally opposite direction, wherein the second diameter is greater than the first diameter; an inner protective cap 12 connectable to the first portion, and an outer protective cap (seen as elements 1,2,4) connectable to the second portion, wherein the term "cap" is defined according to Merriam-Webster dictionary as "something that service as a cover or protection especially for a tip, knob, or end" or "a fitting for closing the end of a tube" or "an overlaying or covering structure", therefore elements 1,2,4 are seen to be a cap, also see figures 4-8 for turning.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP P2000-84078A as applied to claim 4 above and further in view of Kakiuti (EP 749760B1). Now even though the Japanese Patent does not explicitly disclose the use of a first and second protective cap attention is directed to Kakiuti. The Kakiuti reference teaches the use of a first and second cap in figure 5. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of JP P2000-840178A with the teachings of Kakiuti in order to reinforce the inner cap and to provide another safety precaution to help avoid accidental sticks from the needle.

3. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP P2000-84078A as applied to claim 9 and further in view of MPEP 2144.04 VI Section B. Now even though JP P2000-

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84078A does not explicitly disclose the use of a second latching element attention is directed to MPEP 2144.04 VI Section B, Duplication of Parts. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify JP P2000-84078A to have a second latching element in order to provide more security with keeping the cap on over the needle.

With respect to claims 15-17, wherein the connection element is elements 10 & 11, wherein the threads are fully capable of connecting the cannula support to a pen since several pens utilize threads to connect to a cannula support.

4. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP P2000-84078A in view of Sellar (US Patent No. 1050042) and further in view of Kakiuti (EP 0749760B1). The JP reference discloses a needle cover comprising a needle support carrying a needle, the needle support comprising a cam 13, a thread (10,11) for coupling the support to an injection device, and a thread (15,16) for coupling to a cap 12 which also has a thread (18,19) and a cavity on an inside surface. Now even though the JP reference does not disclose the threads to be on an inner surface attention is directed to Sellar. The Sellar reference teaches the use of an inner thread for a needle support to connect to a syringe. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of JP with the teachings of Sellar in order to provide a needle support with a connector that can be utilized with other types of syringes. Now even though the Japanese Patent does not explicitly disclose the use of a first and second protective cap attention is directed to Kakiuti. The Kakiuti reference teaches the use of a first and second cap in figure 5. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of JP P2000-840178A with the teachings of Kakiuti in order to reinforce the inner cap and to provide another safety precaution to help avoid accidental sticks from the needle.

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*Response to Arguments*

Applicant's arguments filed 6/1/2007 have been fully considered but they are not persuasive. Applicant argues that Yasumichi does not disclose a threaded portion, and that Yasumichi discloses instead that "the needle cap may be joined to the needle mounting member in a fitted state by a projection row ... additionally, in the fitted state, the needle cap is provided with a slope having a step capable of coming in contract with the front stepped slope of the needle mounting member." Examiner points applicant to the definition of thread, as provided by Encarta World English dictionary which defines thread as "ridge on screw," and thus Yasumichi's device, though it may not specifically defined as a "thread," can be clearly considered a thread.

*Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine N. Witczak whose telephone number is (571) 272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

cw

*mmw 8/18/07*

KEVIN C. SIMONS  
SUPERVISORY PATENT EXAMINER

*Kevin C. Simons*